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#16

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John P. Parisi
(Print Name)

Date December 22, 1998

(Signature)

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Binggeli et al.

Group: 1613

Serial No. 08/711,339, filed September 6, 1996

Examiner: R. Ramseur

For: **NOVEL PIPERIDINE DERIVATIVES HAVING RENIN INHIBITING ACTIVITY**

COMMUNICATION IN RESPONSE TO SEPTEMBER 25, 1998 FINAL OFFICE ACTION

Nutley, New Jersey 07110
December 22, 1998

Assistant Commissioner for Patents
Washington, D.C. 20231
Box AF

Sir:

This Communication is filed in response to the September 25, 1998 Final Office Action issued in connection with the above-identified patent application. A response to this Office Action is due December 25, 1998.

Applicants request reconsideration and withdrawal of the restriction requirement that was made final in the present Office Action because it does not comply with Patent Office procedure or the law. Applicants point out that a Petition to Commissioner under 37 C.F.R. §1.144 was filed on November 11, 1998 and that a Notice of Appeal is being filed concurrently.

Claims 1-40 and 42-137 are pending in the subject application. Portions of claims 1-17, 20, 32, 33, 35-39, 42-45, 47, 68-72, 74, 77, 87-90, and all of claims 18, 19, 21-31, 34, 46, 48-67, 73, 75, 76, 79-86, and 91-136, have been withdrawn from further consideration under 37 C.F.R. § 1.142(b) because they allegedly are drawn to non-elected inventions. Claims 40, 78, and 137 have been objected to as being dependent upon a non-allowed claim. The Patent Office has not rejected any claim *per se*. However, it is applicants' position that the Patent Office has in fact rejected all of the pending claims as a result of an improper restriction requirement.

In an October 16, 1997 Office Action, the Patent Office issued what was believed by applicants to be an election requirement. In their Amendment dated November 7, 1997, applicants elected a single species for examination purposes, i.e. the compound of claim 137, (3R,4S,5S)-3-(1,4-dimethoxy-naphthalen-2-ylmethoxy)-4-[4-[3-(2-methoxy-benzyloxy)-propoxy]-phenyl]-piperidin-5-ol. In response, the Patent Office in its March 23,

1998 Office Action identified a "generic concept" which was created by the Patent Office to encompass applicants' claimed species. In the present Office Action, the Patent Office made final its restriction requirement that presumably restricts the claimed compounds into two groups: (1) the "generic concept" and (2) all other compounds. However, in view of the "generic concept" approach it is uncertain whether the second group contains a single or many allegedly independent inventions.

The Patent Office does not have the legal authority to create a "generic concept" and require applicants to limit a particular claim to the subject matter indicated as being allowable, i.e. claim 1 as limited to embrace the generic concept.¹ The Patent Office has failed to follow both its own internal procedures as set forth in the MPEP and the law in making the restriction requirement and withdrawing the mentioned claims from consideration. Accordingly, applicants traverse the Patent Office's withdrawal of the mentioned claims from consideration and request reconsideration of the restriction requirement made final in the Office Action.

Procedures for making an election of species are described in MPEP 809.02.

Applicants made a species election in response to this Office Action. As set forth in

¹ The "generic concept" refers to the subject matter of claim 1 limited to where R¹ is aryl optionally substituted by lower alkyl, lower alkenyl, trifluoromethyl, lower alkoxy, hydroxy-lower alkoxy, alkoxy-alkoxy; R² is phenyl or naphthyl each substituted by -O-C₁₋₈ alkylene or -O-C₁₋₈ alkylene-aryl wherein aryl

MPEP 809.02, the Patent Office is required to perform a search for all claims readable on the elected species, including applicants' claim 1 in the present situation. The MPEP does not authorize the Patent Office to derive "a generic concept as depicted in claim 1" to be carved out of existing claims. Therefore, the Patent Office has not followed its own internal procedures.

Applicants have the right under U.S. patent law to claim their invention using the limitations that they regard as essential to delineate the invention, as long as the requirements of 35 U.S.C. §112 are met. The Patent Office pointed out in the Office Action that "[t]he issue here is one of restriction." Thus, the restriction requirement was made solely under 35 U.S.C. §121 and not under some other doctrine such as "improper Markush rejections and to MPEP 803.02" (see page 2 of the Office Action).

It is well-established law that **restriction within a single claim cannot be sustained under 35 U.S.C. §121**. As is stated in *In re Weber*, at pages 331-332,

"§121 provides the Commissioner with the authority to promulgate rules designed to *restrict an application* to one of several claimed inventions when those inventions are found to be "independent and distinct." It is not, however, provide a basis for the Examiner acting under the authority of the Commissioner to *reject a particular claim* on that same basis." (Emphasis in original text.)

is as defined for R¹; X is O, S; Z is lower alkylene; Q is absent; m is O (W is absent); R³ is hydrogen; R⁴ is OH.

In the subject application, the Patent Office made the exact type of restriction requirement expressly forbidden by the CCPA in *In re Weber* (such restriction is tantamount to a rejection). There is no basis under 35 U.S.C. §121 to restrict claim 1 and the subsequent generic claims encompassing the species of claim 137 in the manner set forth by the Patent Office.

Withdrawal of applicants' claims, and in particular claim 1, from further consideration due to an intraclaim restriction requirement amounts in fact to a rejection, see *In re Hass*, 179 USPQ 623, 625 (CCPA 1973). Thus, if the Patent Office does not reconsider the restriction requirement, applicants would be entitled to appeal to the Board of Patent Appeals and Interferences. This proposition is upheld in *In re Weber* at 332.

As in *In re Hass*, the claims in the present application are being withdrawn from consideration not only in this application but also prospectively in any subsequent application because of their content. As the Patent Office's "generic concept" is constructed, it would be impossible for applicants to garner in subsequent patent applications the remainder of the claims after the "generic concept" is cleaved out, especially with regard to the written description requirement. *In re Weber* at 331 states

If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the sub-genera would be defined by the examiner rather than the applicant, it is not inconceivable that a number of the fragments would not be described by the specification.

In view of the above, applicants request that the restriction requirement be withdrawn. In particular, applicants request that the intra-claim restriction requirements be withdrawn since such restriction is prohibited both under the law and under Patent Office policy as set forth in the MPEP.

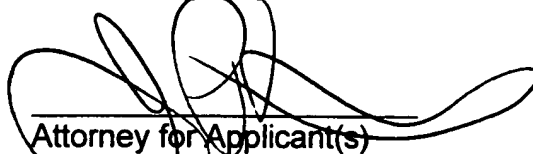
Applicants made a request for reconsideration of the restriction requirement as provided for under 37 C.F.R. §1.143 in their Communication dated July 16, 1998.

For completeness, applicants request that the Examiner consider documents A2, A3, B2 and B3 and initialed Forms 1449 be returned to applicants.

Serial No. 08/711,339
Filed: September 6, 1996
Page -7-

No fee is required in connection with the filing of this Communication. If any fee is deemed necessary, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'John P. Parise', is written over a horizontal line that serves as a separator between the signature and the printed name below.

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